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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed December 15, 2005 is acknowledged and has been entered. Claims 1, 6, and 10 have been amended. Currently, claims 1-6 and 9-11 are pending and are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

3. In light of Applicant's amendment, the rejection of claims 1-6 and 9-11 under 35 U.S.C. 112, second paragraph as being indefinite, is hereby, withdrawn.

4. In light of Applicant's amendment, the rejection of claims 1-6 and 9-11 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, is hereby, withdrawn.

Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for feeding rats a fat-containing diet having an amount of liposome-encapsulated immunoglobulin against lipase effective to reduce their body weight gain, does not reasonably provide enablement for a method wherein any and all animals that are fed the liposome-encapsulated immunoglobulin against lipase is effective to reduce body weight gain in any and all animals, as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The nature of the invention- the invention is directed to a method for feeding an animal a fat-containing diet having an amount of a liposome-encapsulated immunoglobulin against lipase effective to decrease body weight gained due to consumption of the diet relative to a control animal.

The state of the prior art- the prior art of record fails to disclose a method for feeding an animal a fat-containing diet that would have an amount of a liposome-

encapsulated immunoglobulin against lipase that is effective in decreasing body weight gained due to consumption of the diet relative to a control animal.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the claimed method would work in effectively decreasing body weight gained in any and all other animals other than rats, as shown in the examples where the rats are fed a high fat diet. There is no predictability based on the instant specification that the effect of liposome-encapsulated immunoglobulin against lipase to rats extends in direct correlation to all other animals from different species, having different sizes, weights, and physiologic make-up, as encompassed by the claimed invention.

The amount of direction or guidance present- appropriate guidance is provided by the specification for the claimed method to effectively decrease body weight gained in rats that are fed a fat-containing diet. However, the specification fails to provide guidance and direct correlative relationship between rat and all other animals including humans, to enable the claimed method in effectively decreasing body weight gained after consumption of the fat-containing diet having liposome-encapsulated immunoglobulin against lipase.

The presence or absence of working examples- working examples are provided in the specification that show a reduction in weight gain in rats after being fed a high fat diet using the claimed method. There are no working examples that show analogous results in other animals, including humans, that have been fed the fat-containing diet having liposome-encapsulated immunoglobulin against lipase, and which have

effectively decreased their body-weight gained after consumption of the diet, which is encompassed by the breadth of the instant claims.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the method as claimed, considering the genus of animal types encompassed by the claimed invention.

The relative skill of those in the art-the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to a method that is applicable in decreasing body-weight gained by any and all animals, after being fed a fat-containing diet that would have an amount of liposome-encapsulated immunoglobulin against lipase that is effective to reduce body-weight gained due to consumption of the diet.

While the specification exemplifies a reduction in weight gain in rats that have been fed a fat-containing diet using the claimed method, the specification does not show working examples of the claimed method for feeding any and all animals the fat-containing diet having an amount of liposome-encapsulated immunoglobulin against lipase that effectively reduced body-weight gained for the representative animals including humans, after consumption of the diet. The fact that the claimed method appears to work effectively in rats is not sufficient to enable the breadth of the claimed method that warrants applicability and unequivocal effectivity for any and all animals, as that for the rats. Additionally, the specification has not established a correlative relationship between the method's effectivity upon rats in comparison to that of other animals having distinct sizes, weight, and dietary requirements, which would lead the

skilled artisan to conclude that the established effective amount of liposome-encapsulated immunoglobulin against lipase in rats, taking size, weight, and physiological make-up into consideration, would be in direct relationship with that for any and all other animals, including humans.

The specification does not provide a teaching that suggests that rats can be considered an acceptable animal model warranting effectivity of weight-gain decrease in any genus of animal including humans, after consumption of fat-containing diet. Page 3 of the specification makes reference to controlling weight in mammals, avians, and any animal having a pancreas or that secretes lipase using the claimed method, but provides no evidentiary showing of its actual effectivity in other animals than rats, that is representative of other species, sizes, and dietary requirements. While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed method is enabled. This is not the case in the instant specification. Thus, the claimed method is only enabled for effectively reducing body-weight gained in rats by feeding them fat-containing diet having an effective amount of liposome-encapsulated immunoglobulins against lipase, after consumption of the diet.

In view of the teachings of In re Wands, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue. It has been set forth above that 1) the experimentation required to enable the claimed method for any and all animals that are fed a fat-containing diet having liposome-encapsulated immunoglobulin against lipase effective to reduce body-weight gained,

would be great, as 2) there is no experimental evidence provided that would indicate that the claimed method would work in reducing body-weight gained in all other animals, other than rats; 3) there is no proper guidance that shows that rats are acceptable animal models for any and all animals in the instant specification, 4) the nature of the invention is a method that would effectively decrease body-weight gained in animals by feeding them a fat-containing diet having liposome-encapsulated immunoglobulin against lipase effective to decrease body-weight gained, after consumption of the diet, 5) the relative skill of those in the art is high, yet 6) the state of the prior art has been shown to be unpredictable as evidenced by the fact that no prior art has been cited that shows effective reduction of body-weight gained in animals after feeding them a fat-containing diet having an amount of liposome-encapsulated immunoglobulin against lipase, and lastly, 7) the claims broadly recite a method wherein any animal can be fed a fat-containing diet, that would have an amount of liposome-encapsulated immunoglobulin against lipase effective to decrease body-weight gained, without specifically stating how this can be done for every animal genus there is, without undue experimentation.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not provide a teaching of an interaction, i.e. binding or reaction, that takes place between immunoglobulins against lipase and lipase antigen in the gastrointestinal tract to enable decrease of body-weight gained in any and all animals by feeding them a fat-containing diet having effective amount of liposome encapsulated immunoglobulin against lipase. A general comment at page 1, lines 9-10 in the specification states that lipases hydrolyze a portion of dietary lipid, i.e. triacyglycerol, to fatty acids and glycerol in the gastrointestinal tract. The specification provides no teaching of how immunoglobulin binding to lipase, if present, causes the active site of the antigen to be inhibited since immunological binding of antilipase antibodies to lipase does not equate to blocking the catalytic epitope of lipase antigen in every genus of animal encompassed within the claimed invention. Therefore, the capability to generate anti-lipase antibodies from lipase of avians that can act upon lipase antigen in any and all animals, to react or bind in such a way that its catalytic epitope is readily blocked, either in the GI tract or systemically in the plasma and reduce weight gained after consumption of a diet, is an unpredictable task.

The structure of avian lipase antigen from which immunoglobulins against lipase are generated from, so as to enable interspecies cross-reactivity with all animals and decrease body weight gained after feeding them a supposedly effective amount of the liposome encapsulated immunoglobulin against lipase as required by claim 1, is not characterized and described in the specification. General comments on the development and generation of antilipase polyclonal antibodies from avian eggs are insufficient to establish the nature or potency of the antibodies to provide interspecies cross-reactivity with lipase of any or all animals having distinct sizes and dietary requirements for purposes of reducing body-weight gained after consumption of fat-containing diet. Generation of antibodies that react or bind with lipase of any and all species, specifically at its catalytic site, so as to reduce body-weight gained after consumption of fat-containing diet, would appear to be an unpredictable task. Further, physiological function and metabolism between animals and between species may account for enhanced or reduced functional potency of the immunoglobulins against lipase in reacting with a given lipase structure. Thus, one skilled in the art would reasonably conclude that even if one has knowledge in generating antilipase antibodies from avian species such as set forth in Applicant's disclosure, their differential effectivity towards every given species, appears to require further consideration.

Response to Arguments

7. Applicant's arguments filed December 15, 2005 have been fully considered but they are not persuasive.

A) Applicant argues that data obtained using rat as a model is reasonably expected to predict seeing a similar effect of the antibody on other animal species because similar results have been reported in the literature. Applicant provides three references to support their point which teach distinct antibodies providing analogous results between rat and other species.

In response, different immunoglobulins or antibodies have distinct specificities, reactivities, affinities, and effects upon antigens or proteins upon which they bind; hence, an antibody reactive upon a specific antigen cannot be characterized in the same way as another antibody towards the antigen upon which it is specific or reactive. Accordingly, it is not reasonable to expect that the anti-CCK hormone antibody and anti-urease antibody upon which Applicant rely, albeit generated from avian protein or antigens as that taught in Applicant's disclosure, will provide analogous results as anti-lipase antibody towards lipase antigens from different animal species. Specifically, the claims are not only drawn to feeding to an animal a fat-containing diet having an amount of a liposome-encapsulated avian anti-lipase antibodies that can bind or react with any lipase antigen, but is also required to be effective in decreasing body-weight gained in the animal after consumption of the diet. The effectiveness appears to be applicable in amounts of 25-1000 mg/kg of the liposome encapsulated immunoglobulin against lipase. Nowhere in the specification provides that such specific concentrations are applicable or in direct correlation with other animals having distinct sizes, weight, dietary requirements, and physiological make-up. Accordingly, the breadth of the claims in as

far as enablement and adequacy of description are concerned, are limited to effectiveness of the claimed method to that of feeding rats.

Prior Art

8. Currently, claims 1-6 and 9-11 are clear of the prior art of record.

9. For reasons aforementioned, no claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gailene R. Gabel
Patent Examiner
Art Unit 1641
March 1, 2006